PCV29

RANDOMISED, FLEXIBLE DOSE STUDY TO COMPARE THE EFFICACY AND SAFETY OF NIFEDIPINE SUSTAINED RELEASE WITH GINGKGO BILOBA EXTRACT TO TREAT PATIENTS WITH PRIMARY RAYNAUD'S PHENOMENON; KOREAN RAYNAUD (KOARA) STUDY

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OBJECTIVES: To compare the efficacy and safety of a nifedipine sustained release (nifedipine SR), with ginkgo biloba extract as treatment for primary Raynaud's phenomenon in Korean. **METHODS:** ; Multi-centred, randomised, flexible dose and open study. A total of 134 patients with primary Raynaud's phenomenon were selected from 3 centers and randomly assigned to either the Nifedipine SR group (Group N) or the Ginkgo biloba extract group (Group G) in the ratio of 2:1. After a run-in period of two weeks, participants received treatment for eight weeks. Primary efficacy evaluation was any percent change of the Raynaud attack rate between the reference value before treatment and after the 8-week treatment. A safety was also evaluated. **RESULTS:** ; Out of 134 patients with primary Raynaud's phenomenon, 39 subjects dropped out of the program during the selection period. Ninety-three subjects (70.5% of the original pool) were randomly assigned, and 64 subjects (Group N: 42, Group G: 22) among the 93 completed this clinical trial. There were 24 male subjects (25.81%) and 69 female subjects(74.19%), and the average age of the subjects was 39.20 (Group N: 37.67, Group G: 42.13). The percent change of the attack rate in Intention To Treat (ITT) group was 50.05% at 7 and 8 weeks after treatment in Group N, while it was just 31.02% in Group G (p-value = 0.03). The improvement was shown to be much higher in Group N than in Group G. No difference in QOL items was found between the two groups in this clinical trial. No significant adverse events occurred; severity of the adverse events incurred was mostly mild, and those adverse events were improved without specific treatment. **CONCLUSIONS:** Nifedipine SR was more effective pharmacotherapy than Ginkgo biloba for primary Raynaud's phenomenon (Percent change of R : 50.1% vs. 31%). Both Nifedipine SR and Ginkgo biloba showed tolerability without serious adverse events.

PCV30

THE ASSOCIATION OF ASPIRIN USE ON RISK OF HOSPITALIZATION IN CHF PATIENTS TAKING ACE INHIBITORS: A RETROSPECTIVE ANALYSIS OF A NATIONAL COHORT OF VETERANS

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OBJECTIVES: Aspirin may interact with ACE inhibitors to reduce their beneficial effects in patients with heart failure. The objective of this retrospective cohort study was to assess the risk of congestive heart failure (CHF) hospitalization in patients with heart failure (HF) taking ACE inhibitors in a large national cohort of veterans. **METHODS:** Exposure to aspirin was assessed between October 1, 2000 and September 30, 2001. Patients were characterized as prescribed: no aspirin, low-dose (≤ 81 mg) aspirin, high-dose (>81 mg) aspirin. Time to HF hospitalization in these selected patients was assessed between October 1, 2001 and September 30, 2002. Chi-square tests, Kaplan-Meier plots and log-rank tests were employed for testing bivariate associations. A multivariable Cox regression model was used to estimate the adjusted hazard ratio for the risk of CHF hospitalization due to aspirin exposure after controlling for sociodemographic factors, comorbidities, comedications, and years with HF. **RESULTS:** The final study cohort consisted of 157,088 HF patients with a mean age of 69.75 (± 10.19) years. The crude HF hospitalization rates differed significantly between the treatment groups (log-rank statistic for KM plot: p-value <0.001). In multivariate analysis of the association of aspirin use and hospitalization for CHF the use of both high-dose aspirin (HR 1.26, 95% CI 1.19–1.34) and low-dose aspirin (HR 1.18, 95% CI 1.09–1.27) was associated with increased risk of CHF hospitalization with no aspirin use as the reference group. The results remained the same for high-dose aspirin in case of patients: with both CHF and IHD, without IHD, age < 65 years, age ≥ 65 years and patients with Medication Possession Ratio (MPR) ≥ 0.8. **CONCLUSIONS:** The theory of negative interaction between ACE inhibitors and aspirin may be true, but results must be interpreted with caution. Prospective studies would be needed to investigate this interaction further.

CARDIOVASCULAR DISORDERS – Cost Studies

PCV31

US BUDGET IMPACT OF INCREASING ASPIRIN USAGE FOR PRIMARY AND SECONDARY PREVENTION OF CARDIOVASCULAR DISEASE

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OBJECTIVES: Cardiovascular disease (CVD) is a leading cause of death in the US, but regular use of preventive low-dose aspirin has proven to be an effective way to prevent CV events. The purpose of this study was to explore the potential economic impact in the US if aspirin usage were to be increased in line with current clinical guidelines for primary and secondary prevention of CV events. **METHODS:** The risk profile of the US population was modeled using NHANES data and the Framingham cardiovascular risk equations were applied to calculate risk for myocardial infarction, angina and stroke according to age and gender. Primary and secondary prevention patient populations were considered separately. Using publicly available unit costs, a budget impact model calculated the annual impact of increased preventive aspirin usage considering adverse events and diminishing aspirin adherence over a ten-year time horizon. **RESULTS:** In a base population of 1,000,000 patients, implementation of current clinical guidelines would prevent an additional 1273 myocardial infarctions, 2184 angina episodes and 565 strokes in primary prevention patients and an additional 578 myocardial infarctions, and 607 strokes in secondary prevention patients. Angina reduction was not assessed in secondary prevention patients. This represents a total savings to the Managed Care Organization (MCO) of $84.9 million for primary prevention and $32.7 million for secondary prevention and additional out of pocket expense to patients of $32.1 million for primary prevention and $2.9 million for secondary prevention for the cost of aspirin. **CONCLUSIONS:** This model suggests that there is a strong economic case, both for payers as well as for society, to encourage aspirin use for patients at appropriate risk and per clinical guidelines. It also provides an example of how minimizing costs does not necessarily have to imply rationing of care.

PCV32

HEALTH ECONOMICS EVALUATION ON PERCUTANEOUS CORONARY INTERVENTION(PCI) IN CHINA

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OBJECTIVES: In China, increasing CHD patients accept PCI treatment, with about 40% GR annually from 1984 to 2005; however, some have alleged that it was abused. Further, the China Basic Medical Insurance (BMI) Authority also felt financial pressure due to the escalating use. Therefore, the China Health Insurance Research Association (CHIRA) decided to evaluate the value of coronary stenting as the evidence for appropriate regulation. **METHODS:** This observational, prospective study involved 20 sites (13 cities). A total of 630 of 720 planned cases were recruited from July 2005 to July 2006 with one year follow up. The study evaluated clinical and economic value of stenting by collecting clinical, cost, and QoL data. Retrospective data collected included reimbursement policy and actual claim data in 2005 and first half of 2006, to estimate the economic burden and budget impact and to analyze the cost-influence factors. **RESULTS:** 1) There was generally not evident abuse in PCI/stenting in the available data; 2) The effectiveness of PCI/stenting is favorable, with 1.43% complication, 0.98% death, 0.82% incidence of MI, and 1.79% of revascularization. All SEs are significantly lower than those seen published rates. The QoL scores improved significantly (+20, SF-36); 3) Stenting can gain $7100 per incremental QALY; 4) PCI fees are influenced considerably by the number of diseased vessels, co-morbidity, and reimbursement policy; 7) The price of PCI is lower than its cost, and thus it's mainly reimbursed by pharmaceutical and device use; and 8) the economic burden of PCI was heavy in 2006. The out-of-pocket part of PCI was equal to an employee's average annual salary or twice that of a retiree's pension. **CONCLUSIONS:** Stenting is cost effective with favorable QoL improvement. Therefore, it's worthwhile to further improve reimbursement regulations to release a patients' economic burden.

PCV33

A LIFE-LONG COST-EFFECTIVENESS MARKOV MODEL COMPARING HIGH-DOSE VERSUS STANDARD DOSE STATIN THERAPY IN ACUTE CORONARY SYNDROME PATIENTS

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OBJECTIVES: To construct a flexible Markov model allowing cost-effectiveness analysis of different statin therapies over different time horizons in ACS patients in Germany. **METHODS:** A Markov model was designed to compare outcomes of intensive atorvastatin 80 mg versus standard simvastatin 20–40 mg treatment. Event rates for the first 5 years for MI, stroke, unstable angina, heart failure, revascularization and cardiovascular death were derived from a post-hoc analysis of a subset of patients with recent ACS in the IDEAL study; extrapolation of event rates beyond the trial was based on risk-prediction equations from the Framingham study. Event and all-cause mortality were based on sources in literature. To estimate QALYs, utilities were derived from the literature. Cost inputs were based on the German statutory health insurance perspective; patients' co-payments were deducted. Costs of care for cardiovascular events were based on DRG costs for acute treatment, and on literature and expert panel results for subsequent costs. Univariate and probabilistic sensitivity analyses were performed. All costs and benefits were discounted by 5% annually, and costs were reported in 2008 Euros. **RESULTS:** The base case used a one-year cycle length, a lifetime time horizon, and a five-year treatment duration with high-dose atorvastatin, after which all patients received simvastatin for life. For the base case, the incremental cost per life-year gained is €13,993, and the incremental cost per QALY gained is €14,168. At a threshold of €30,000 per QALY gained, sensitivity analysis predicted an 85% probability that atorvastatin 80 mg would be considered cost-effective compared with simvastatin 20–40 mg. **CONCLUSIONS:** The results can

only approximate real-life clinical practice; however, the carefully constructed model and selection of input parameters, combined with data based directly on a post-hoc analysis of a clinical trial, make this a useful contribution to the debate regarding the incremental benefit of intensive statin therapy.

PCV34

FINANCIAL ASSESSMENT OF A COMPREHENSIVE CARDIAC CARE PROGRAM FOR PATIENTS WITH OCCULSIVE CORONARY ARTERY DISEASE

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OBJECTIVES: To assess the financial impact of a comprehensive cardiac care (CCC) program on total health care expenditures after an initial coronary event. **METHODS:** This was a matched, retrospective analysis of a nurse- and pharmacist-managed CCC program that was designed to provide evidence-based lifestyle and medication support at the earliest opportunity after a coronary event. Patients with an incident occlusive CAD event between January 1999 and June 2004 were categorized into intervention and comparator groups, respectively, by enrollment or never enrollment (No CCC) into the CCC. Patients were matched 1:1 on chronic disease score (CDS) and 180-day pre-coronary event (baseline) total health care expenditures. Pharmacy and medical utilization events were extracted from electronic administrative and claims databases. Utilization events were collected after the initial coronary event until death, health plan termination, three years, or December 31, 2005, whichever came first (follow-up). Expenditure estimates from the Kaiser Permanente Decision Support System (in 2007 dollars) were applied to utilization events. An intervention cost of $1/follow-up-day was applied to all CCC patients. Expenditures/day were modeled with adjustment for matching variables, patient characteristics, baseline expenditures, and intra-correlations of matched patients. **RESULTS:** A total of 628 CCC patients were matched to 628 No CCC patients. Patients in the No CCC group were slightly older, more likely to be female, and to have had a myocardial infarction. Mean/median baseline expenditures and CDS were equivalent. During follow-up, 12 and 98 cardiac-related deaths occurred in and mean/median total health care expenditures/day were $57/$30 and $159/$45 for the CCC and No CCC groups, respectively (both $p < 0.001$). After adjustment, CCC patients were associated with $103/day lower total health care expenditures ($p < 0.001$; adjusted R-square = 0.71 with log-transformed expenditures). **CONCLUSIONS:** Comprehensive and aggressive implementation of secondary cardiac prevention strategies with close monitoring and follow-up of CAD patients is associated with reduced health care expenditures.

PCV35

PHARMACOECONOMIC MODEL OF ENOXAPARIN VERSUS HEPARIN FOR PREVENTION OF VENOUS THROMBOEMBOLISM IN MEDICAL PATIENTS

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OBJECTIVES: Venous thromboembolism (VTE) causes significant morbidity and mortality and represents a huge health economic burden. Although enoxaparin has some advantages over unfractioned heparin (UFH), both are recommended for prophylaxis of VTE according to the guidelines from the Brazilian Medical Association. We present a tool to aid in selecting among similarly effective agents for VTE prophylaxis. The costs of UFH and enoxaparin to prevent venous thromboembolism in medical patients in the Brazilian treatment environment were compared. **METHODS:** A decision model was used in a pharmacoeconomic comparison of enoxaparin and UFH, each given for seven days, for the prophylaxis of VTE in medical patients. In the model four main outcome pathways could follow prophylaxis: major bleeding, proximal deep venous thrombosis (with or without pulmonary embolism), distal deep venous thrombosis (DVT), and no DVT. False-negative or false-positive clinical diagnoses of VTE were also taken into account. Probabilities of thromboembolic events and major bleeding were derived from published randomized clinical trials and meta-analysis. Costs were calculated using the microcosting technique and the administrative health care claims database of a major Brazilian Health Maintenance Organization from July, 2007 to June, 2008. The claims represented a full range of health plans levels at different hospitals. Only the costs related to the VTE prophylaxis and adverse events, acute VTE diagnosis, treatment and complications were considered. **RESULTS:** Enoxaparin dominated UFH. There were cost savings of 74,121 Brazilians reais per 1,000 patients by using enoxaparin instead of UFH for prophylaxis of VTE. The base-case analysis also demonstrated that the extra costs in the UFH group were mainly related to the management of hemorrhagic adverse events. **CONCLUSIONS:** This model of enoxaparin versus UFH for VTE prophylaxis in medical patients showed that enoxaparin was less costly than UFH in overall expected costs from the hospital perspective.

PCV36

THE IMPACT OF A STATIN FORMULARY CHANGE ON HEALTH OUTCOMES AND MEDICAL COSTS

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OBJECTIVES: To determine the effect of a formulary change in the statin drug class on health outcomes and disease-specific health care costs. **METHODS:** A retrospective cohort design was implemented using pharmacy and medical claims data from a large national employer group. Patients (n = 330)with one or more claims for atorvastatin or another statin during the six months prior to a formulary change on January 1, 2006 were identified and evaluated. The formulary change was implemented for all patients however, only those patients taking atorvastatin were affected. Cardiac-related medical events (tests, doctor visits, outpatient facility visits, and acute cardiovascular events) and disease-specific costs during the year following the formulary change were measured. The impact of formulary change on cardiac-related medical events and disease-specific costs were evaluated using multivariate analysis controlling for gender, age, comorbidity status, and drug indication (primary vs. secondary prevention). **RESULTS:** Of the 330 patients, 180 (55%) used atorvastatin prior to the formulary change. After the implementation of the formulary change, 146 (81%) of patients switched to a preferred statin drug, 19 (10%) discontinued statin therapy, and 16 (9%) continued taking atorvastatin as a non-preferred drug. There were no significant differences in the proportions of patients with cardiac tests ($p = 0.70$), doctor's visits ($p = 0.64$), outpatient facility visits ($p = 0.52$), or acute cardiovascular events ($p = 0.13$) in the year after the formulary change between patients with pre-formulary change claims for atorvastatin or another statin. There were no statistically significant differences in health care costs among patients with pre-formulary change claims for atorvastatin or another statin after adjustment for covariates (OR = 0.89, 95% CI: 0.41–1.92). **CONCLUSIONS:** Changing the formulary status of atorvastatin does not appear to adversely affect the total medical costs or utilization of cardiac-related health care services.

PCV37

ECONOMIC IMPACT OF EDARAVONE THERAPY FOR PATIENTS WITH LACUNAR INFARCTION IN JAPAN

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OBJECTIVES: Edaravone (Radicut®), which was first approved in Japan in June 2001 as a free radical scavenger, is used widely for the treatment of acute ischemic stroke in Japan. The purpose of this study was to estimate the economic impact of edaravone therapy in Japan based on results of a meta-analysis of edaravone therapy for patients with lacunar infarction. **METHODS:** Japanese patients with lacunar infarction aged 35 years or older were included in this analysis. We compared the economic impact of treatment for lacunar infarction between the edaravone group (E group) and the non-edaravone group (non-E group). For the basic information on patient status for this analysis, we used previously published meta-analysis data on the modified Rankin Scale (mRS) distribution 1 month or more after the occurrence of lacunar infarction. Four types of costs were considered: hospitalization costs for lacunar infarction therapy, nursing-care costs after hospital discharge, and productivity costs during hospitalization and due to work loss. **RESULTS:** The total costs per patient with lacunar infarction in the E and non-E groups were US$42,054 (1US$ = 92 JPY) and US$47,270, respectively, and the potential cost savings for using edaravone therapy was estimated at US$5,216. The breakdown of total costs in the E and non-E groups, respectively were for hospitalization costs: US$10,215 (24.3%), and US$8,150 (17.2%), nursing-care costs: US$14,779 (35.1%), and US$18,256 (38.6%), decreased productivity costs due to hospitalization: US$1,956 (4.7%), and US$2,065 (4.4%), and those due to work loss: US$15,105 (35.9%), and US$18,691 (39.5%). **CONCLUSIONS:** In this analysis, edaravone therapy for patients with lacunar infarction was ultimately a promising cost saving therapy compared with other therapies that did not use edaravone, as it avoided nursing-care costs and productivity loss despite being more expensive during acute treatment.

PCV38

COST-EFFECTIVENESS OF RIVAROXABAN VERSUS ENOXAPARIN FOR PROPHYLAXIS AFTER TOTAL HIP OR TOTAL KNEE REPLACEMENT IN KOREA

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OBJECTIVES: To assess the cost-effectiveness of oral rivaroxaban versus subcutaneous enoxaparin for prevention of venous thromboembolism (VTE) following total hip replacement (THR) or total knee replacement (TKR) in Korea. **METHODS:** An economic model was developed to evaluate the clinical and economic consequences of rivaroxaban versus enoxaparin, based on the RECORD2 and 3 randomized controlled trials. RECORD2 compared a 35-day course of rivaroxaban with a 12-day course of enoxaparin in THR, while RECORD3 compared 12-day courses of rivaroxaban and enoxaparin following TKR. In RECORD2, rivaroxaban reduced total VTE (composite: any deep vein thrombosis, non-fatal pulmonary embolism and all-cause mortality) by 79% and symptomatic VTE by 80% versus 12-day enoxaparin. In RECORD3, rivaroxaban reduced total VTE by 49% and symptomatic VTE by 66% versus enoxaparin. Occurrence of major bleeding was similar with both agents. The model accounted resource use according to primary research data and included direct medical costs from the Korean Health Insurance Review Agency. Utilities were derived from published literature and clinical and economic outcomes were discounted at a 5% annual rate in line with Korean guidelines. The model reported effectiveness outcomes in quality-adjusted life years (QALYs) and costs in Korean Won (KRW) and was run over a five-year time horizon. **RESULTS:** In THR, rivaroxaban demonstrated per-patient cost savings of KRW 40,803 versus enoxaparin and a gain of 0.0027 QALYs per patient. In TKR, rivaroxaban reduced per-patient costs by KRW 27,692 and resulted in a gain of 0.0019 QALYs per patient. Cost savings in the rivaroxaban arm